(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
12 May 2005 (12.05.2005)

PCT

(10) International Publication Number
WO 2005/041799 A1

(51) International Patent Classification[7]: A61B 17/88, 17/70

(21) International Application Number: PCT/US2004/035000

(22) International Filing Date: 21 October 2004 (21.10.2004)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
10/690,211 21 October 2003 (21.10.2003) US

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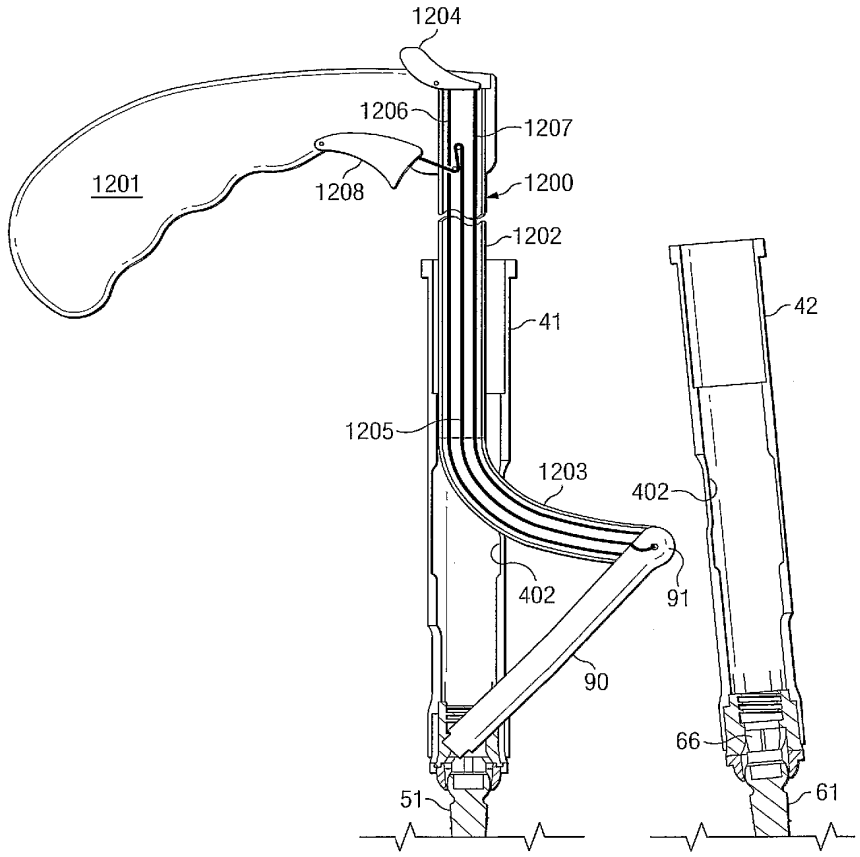
(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI,

[Continued on next page]

(54) Title: SYSTEM AND METHOD FOR STABILIZATION OF INTERNAL STRUCTURES



(57) Abstract: There is shown a system and method for reducing the difficulty in percutaneous placement of a spine stabilization brace by coupling the brace to a pedicle screw in a single assembly. The brace-screw assembly is delivered along with an anchor extension through a cannula for anchoring in the vertebrae pedicle. The anchor extension becomes a cannula for working on the brace from the exterior of the patient, as constructed with a slot opening along two sides. Once the screw portion of the bracescrew assembly is locked in place with respect to the first vertebra, the proximal end of the brace is below the skin line. The brace is then repositioned so that the proximal end leaves the cannula through one slot and is captured by a corresponding slot positioned in a second cannula coupled to a second anchor. Once captured, the proximal end of the brace is guided by the second cannula to a receptacle positioned in the second vertebra.

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FR, GB, GR, HU, IE, IT, LU, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Declarations under Rule 4.17:

— *as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii)) for the following designations AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, UZ, VC, VN, YU, ZA, ZM, ZW, ARIPO patent (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG)*

— *as to the applicant's entitlement to claim the priority of the earlier application (Rule 4.17(iii)) for the following designations AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, UZ, VC, VN, YU, ZA, ZM, ZW, ARIPO patent (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG)*

Published:

— *with international search report*

— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments*

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SYSTEM AND METHOD FOR STABILIZING OF INTERNAL STRUCTURES

TECHNICAL FIELD

[0001] This invention relates to bony structure stabilization systems and more particularly to systems and methods for percutaneously inserting a pedicle screw stabilization device.

BACKGROUND OF THE INVENTION

[0002] The human spine provides a vast array of functions, many of which are mechanical in nature. The spine is constructed to allow nerves from the brain to pass to various portions of the middle and lower body. These nerves, typically called the spinal cord, are located in a region within the spine called the neuro canal. Various nerve bundles emerge from the spine at different locations along the lateral length of the spine. In a healthy spine, these nerves are protected from damage and/or undue pressure thereon, by the structure of the spine itself.

[0003] The spine has a complex curvature made up of a plurality (24 in all) of individual vertebrae separated by intervertebral discs. These discs hold the vertebrae together in a flexible manner so as to allow a relative movement between the vertebrae from front to back and from side to side. This movement then allows the body to bend forward and back and to twist from side to side. Throughout this movement, when the spine is operating properly the nerves are maintained clear of the hard structure of the spine and the body remains pain free.

[0004] Over time, or because of accidents, the intervertebral discs loose height, become cracked, dehydrated, or are simply jarred out of position. The result being that the disc space height is reduced leading to compression of the nerve bundles causing pain and in some cases damage to the nerves.

[0005] Currently, there are many systems and methods at the disposal of a physician for reducing, or eliminating, the pain by minimizing the stress on the nerve bundles. In some instances, the existing disk is removed and an artificial disk is substituted therefore. In other instances, two or more vertebrae are fused together to prevent relative movement between the fused discs.

[0006] Often there is required a system and method for maintaining proper space for the nerve bundles that emerge from the spine at a certain location. In some cases a cage or bone graft is placed in the disc space to preserve height and to cause

fusion of the vertebral level. As an aid in stabilizing the vertebrae, one or more rods or braces are placed between the fused vertebrae with the purpose of the braces being to support the vertebrae, usually along the posterior of the spine while fusion takes place. These braces are often held in place by anchors which are fitted into the pedicle region of the vertebrae. One type of anchor is a pedicle screw, and such screws come in a variety of lengths, diameters, and thread types.

[0007] One problem when connecting the braces to the anchors is to position the braces in place as quickly as possible and without doing more damage to the surrounding tissue and muscle of the patient as is absolutely necessary. For that reason, procedures have been developed that allow the physician to secure the anchors in the bony portion of the spine and to then connect the brace between the anchors. Techniques have been developed to allow the surgeon to perform this procedure in a minimally invasive manner, utilizing a percutaneous method.

[0008] In one such procedure, a first pedicle screw is inserted in a first vertebra to be stabilized. This screw is inserted using a tube, or cannula, extending through the patient's skin to the pedicle portion of the vertebrae. A second pedicle screw is inserted through a second cannula into the second vertebrae to be stabilized. Under current practice, the physician then must work the brace, or other supporting device, so that each brace end is positioned properly with respect to the preplaced pedicle screws. In order to properly position the brace ends fluoroscope pictures are taken as the brace is worked into position. It is difficult for the physician to know the exact orientation of the brace and even to know for certain when the brace ends have been properly positioned. U. S. Patent No. 6,530,929 shows one instrument for positioning a stabilization brace between two preplaced anchors.

[0009] Another problem with both of the approaches discussed above, is that the braces must be made significantly longer than the distance between the pedicle screws to allow for proper attachment of the brace ends to the screws. Placement of the brace is sensitive to anchor alignment since the adjustment establishes the trajectory of the brace. If this trajectory is not established properly, the brace would have to pass through tissue, and, or bone that should not be touched. Also, the brace must enter a separate incision in the back of the patient. In addition to these, the learning curve for

manipulation the insertion device of the '929 patent is greater than what should be required.

[0010] Another, more recent, approach has been to insert the cannulas over the respective pedicle areas of the vertebrae to be stabilized and then measure the distance between the cannulas. This measurement is then used to select, or cut, a rod, adding a bit to the dimension to ensure that the rod can be rigidly affixed to each anchor. In addition, each rod must be bent a certain amount (or a pre-bent rod utilized) to reflect the curvature of the spine. Once the proper rod dimension and shape is obtained each end of the rod is positioned in a separate one of the cannulas and the rod is worked downward toward the anchors passing through a separation of muscle and tissue from the skin line to the pedicle site. This placement of the rod is facilitated by a long handheld gripper which must then be manipulated to position the rod ends over the respective anchors so as to be captured by set screws in the tops of the respective anchors. Proper positioning of the rod ends is difficult, and requires repeated use of fluoroscopy to insure that the rod is fully seated and in a correct position.

BRIEF SUMMARY OF THE INVENTION

[0011] In one embodiment, there is shown a system and method for reducing the difficulty in percutaneous placement of a spine stabilization brace by coupling the brace to a pedicle screw in a single assembly. The brace-screw assembly is delivered along with an anchor extension through a cannula for anchoring in the vertebrae pedicle. The anchor extension, which becomes a cannula for working on the brace from the exterior of the patient, is constructed with partial slot openings along two sides. Once the screw portion of the brace-screw assembly is locked in place with respect to the first vertebrae, the proximal end of the brace is below the skin line. The brace is then repositioned so that the proximal end leaves the cannula through one slot and is captured by a corresponding slot positioned in a second cannula coupled to a second anchor. Once captured, the proximal end of the brace is guided by the second cannula to a receptacle positioned in the second vertebrae. In one embodiment, the distal end of the brace is designed to adjust about the head of the first anchor and is further designed to allow for polyaxial as well as lateral movement, thereby adjusting for relative distances and angles between vertebrae.

[0012] The foregoing has outlined rather broadly the features and technical advantages of the present invention in order that the detailed description of the invention that follows may be better understood. Additional features and advantages of the invention will be described hereinafter which form the subject of the claims of the invention. It should be appreciated that the conception and specific embodiment disclosed may be readily utilized as a basis for modifying or designing other structures for carrying out the same purposes of the present invention. It should also be realized that such equivalent constructions do not depart from the invention as set forth in the appended claims. The novel features which are believed to be characteristic of the invention, both as to its organization and method of operation, together with further objects and advantages will be better understood from the following description when considered in connection with the accompanying figures. It is to be expressly understood, however, that each of the figures is provided for the purpose of illustration and description only and is not intended as a definition of the limits of the present invention.

BRIEF DESCRIPTION OF THE DRAWINGS

[0013] FIGURE 1 is a sketch of the human spine showing a pair of cannulas positioned with respect to two vertebrae;

[0014] FIGURES 2A-2F show a cut-away view showing different stages of the installation of the stabilization device;

[0015] FIGURE 3A shows a side view of two vertebrae;

[0016] FIGURE 3B shows a top view of a single vertebrae;

[0017] FIGURE 4 shows an embodiment of a slated cannula;

[0018] FIGURE 5A shows a brace-anchor assembly within a cannula;

[0019] FIGURE 5B is a cross-section view taken through line 5B-5B of FIGURE 5A;

[0020] FIGURE 5C is a cross-section view taken through line 5C-5C of FIGURE 5A;

[0021] FIGURE 6A shows the receiving cannula attached to a receiving anchor;

[0022] FIGURE 6B is a cross-section view taken through line 6B-6B of FIGURE 6A;

[0023] FIGURE 6C is a cross-section view taken through line 6C-6C of Figure 6A;

[0024] FIGURE 7A shows the brace-anchor assembly of FIGURE 5A with the brace in a brace-down (rotated) position;

[0025] FIGURE 7B is a cross-section view taken through line 7B-7B of FIGURE 7A;

[0026] FIGURE 7C is a cross-section view taken through line 7C-7C of FIGURE 7A;

[0027] FIGURE 8A shows the receiving cannula of FIGURE 6A having captured a brace from an adjacent cannula;

[0028] FIGURE 8B is a cross-section view taken through line 8B-8B of FIGURE 8A;

[0029] FIGURE 8C is a cross-section view taken through line 8C-8C of FIGURE 8A;

[0030] FIGURE 9 shows an embodiment of a hinged brace;

[0031] FIGURE 10 shows an embodiment of a pair of anchors each firmly attached to a brace;

[0032] FIGURE 11 illustrates one embodiment of a screw driver applying force to a brace; and

[0033] FIGURES 12A and 12B illustrate one embodiment of a tool for positioning the brace.

DETAILED DESCRIPTION

[0034] Turning now to FIGURE 1, there is shown a sketch of human spine 10 showing a pair of tubes, or cannulas 41 and 42 extending through skin 101 into vertebrae L5 and L4. Cannula 41 is positioned over the pedicle of vertebrae L5 (as will be discussed), and cannula 42 is positioned over the pedicle of vertebrae L4. This procedure is being illustrated with respect to vertebrae L4 and L5 but could be performed with respect to any vertebrae or with respect to any bony portions of the body (human or animal) where a brace is to be placed between two points. The distance D is variable as desired. The sketch of FIGURE 1, as are the sketches shown in other figures, are not to scale and are shown for illustration purposes with angles selected for clarity of explanation and not necessarily selected to be anatomically correct.

[0035] The procedure to insert the brace between vertebrae L5 and L4 is as follows: The surgeon identifies the desired vertebral levels and pedicle positions via standard techniques. Once the target vertebrae are identified, a small incision 102 is made through skin 101 and a tracking needle (or other device) is inserted to pinpoint exactly where each anchor is to be placed. A fluoroscope, or other x-ray technique, is used to properly position the tracking needle. Once the proper position is located, guide wire (K wire) 22 (FIGURE 2A) is positioned with its distal end against the pedicle, in this case pedicle 37-1 of vertebrae L5. A guide wire 23 may be similarly positioned with its distal end against pedicle 37-1 of vertebrae L4, as shown in FIGURE 2A. The surgeon then slides a series of continuing larger sized dilators 12, 12a, 12b, 12c down guide wire 22, and slides a series of continuing larger sized dilators 13, 13a, 13b, 13c down wire 23 as shown in FIGURE 2B.

[0036] Approximately four or five dilators are used until a diameter suitable for passing the pedicle screw and its extensions is achieved. A tap is sent down over the K wire to tap a hole into the pedicle in preparation for receiving the anchor, which in this case is a pedicle screw. This tap will usually be a size slightly smaller than the pedicle screw thread size selected for that patient and that level.

[0037] After the hole is tapped and the K wire and the inner dilators, such as dilators 13, 13a, 13b, are removed, the surgeon is ready to introduce the anchor into

the vertebrae. As shown in FIGURE 2C, prior to inserting the anchor, brace 90 is attached to screw 51 to form a brace-screw assembly. This assembly is then positioned at the distal end of cannula 41 and a screwdriver or wrench (1101 shown in FIGURE 11) is inserted into cannula 41 and attached to the proximal end 91 of brace 90. The entire assembly is then inserted into dilator 13C. The screwdriver engages with proximal end 91 of brace 90 so as to allow the surgeon to screw pedicle screw 51 into the pre-tapped hole in vertebrae L5. Pressure on the screwdriver forces the screw to be in-line with the brace, which, in turn, is in-line with the screwdriver. The screwdriver can be removeably attached to end 91 of brace 90 by engaging, for example, flat 94 (shown in FIGURE 11) and/or hole 95 (shown in FIGURE 9).

[0038] This same procedure would be repeated for each additional level, in this case level L4, except that screw 61 has assembly 62 affixed thereto. Assembly 62 is adapted to receive proximal end 91 of brace 90 as will be more fully described herein.

[0039] For a single level the above procedure is typically performed first on one side of both vertebral levels and then on the other side. When finished, four pedicle screws are inserted, holding two braces positioned laterally with respect to the center of the spine.

[0040] Once both screws are in place in vertebrae L5 and L4, dilators 12C and 13C are removed and, the surgeon slides a blunt dissection tool into incision 102 (FIGURE 1) and gently parts the muscle bundle below the skin between vertebrae L4 and L5. Alternatively, the blunt dissection tool could go down the second cannula and, starting at the bottom of the second cannula 41, work open the muscle bundle between the cannula working upward as far as is necessary. Using this procedure, the muscles (and other tissue), only need be separated to a point where the brace 90 must pass. Thus, the separation need not go to the skin level. This reduces trauma even further.

[0041] Once an opening in the muscles has been developed between cannulas 41 and 42, brace 90 is then positioned, by pivoting, as shown in FIGURE 2D, by sliding a tool (for example, tool 1200, FIGURE 12A) down cannula 41 to engage proximal end 91 of brace 90. The tool could have a force fit with end 91 or as shown in FIGURE 12A, can have handle 1201 and trigger control 1204 for controlling removable

attachment with brace 90. One or more wires 1205, 1206 and 1207 extending inside tool portions 1202, 1203, can be controlled by triggers 1204 and 1208 so that spring loaded grips (not shown) controlled by wire 1202 can mate with hole 95 (shown in FIGURE 9). Trigger 1208 can control wire 1205 to releasably grip end 91 of brace 90. Once tool portion 1203 is mated with end 91 of brace 90 the surgeon can pull the tool slightly outward to disengage brace end 92 from screw 51. The surgeon can then operate wires 1206 and 1207, via trigger 1204, or otherwise, which wires pull on one side of tool portion 1203 to bend tool portion 1203, as shown in FIGURE 12B. This bending forces brace end 91 out of cannula 41 (through opening 402 thereof) and through the prepared muscle opening and into opening 402 of cannula 42. Once within cannula 42, tool end 1203, under control of the surgeon, manipulates brace end 91 down cannula 42 and into a mating relationship with screw 61. Once this mating relationship is achieved, (as will be discussed) tool end 1203 is released from brace end 91, under control of wire 1205 and tool 1200 is removed from both cannulas. Wires 1206 and 1207 are used on opposite sides of tool 1200 under control of trigger 1208 to control bending and unbending of tool portion 1203. Note that only temporary locking mechanism and/or tool bending mechanism, including pneumatic and hydraulic can be used, if desired.

[0042] Slots 402 of the respective cannulas are positioned fully under the skin line 101 of the patient. Brace 90 can have any shape desired. It can be flat, oval or rod shaped and the cross-section need not be constant in shape or diameter.

[0043] The surgeon receives positive feedback (a sensory event), either by feel (for example, a snap action) or by sound (for example, a click), or both when brace 90 is properly mated with assembly 62. If desired, one or both of assembly 52 or 62 mounted to the respective pedicle screws 51 and 61 can be angularity adjusted (as will be discussed) to accommodate the patient's body structure. The polyaxial nature of assemblies 52 and 62 with respect to the anchors allows for such adjustments which are necessary for a variety of reasons, one of which is that the angulation between adjacent vertebral pedicles varies.

[0044] As shown in FIGURE 2E, after all angular and lateral adjustments are made, set screws 220, or other locking devices, are introduced down cannulas 41 and 42 to lock each end of brace 90 to its respective pedicle screw.

[0045] As shown in FIGURE 2F, once the proximal end of brace 90 is snapped in place to screw 61 and set screws 220 are tightened, cannulas 41 and 42 can be removed and the incision closed. As discussed, this procedure would then be repeated on the opposite side of spinous process 33.

[0046] FIGURE 3A is a lateral view of two vertebrae segments and L5 and L4. Nerve roots 32 are shown coming out from spinal cord 301. The nerve roots become compressed when vertebrae L4 collapses down upon vertebrae L5 when disc 31 becomes reduced in size due to injury, a dehydration or otherwise. Spinous processes 33 form a portion of the posterior of the vertebral bodies.

[0047] FIGURE 3B is a top view of vertebrae L4 and is similar to other lumbar levels. A Vertebra L4 includes vertebral body 36, spinous process 33, neuro canal 34, and transverse processes 35. The pedicle region, such as pedicle 37, is the bony area bridged roughly between outer wall 38 and neuro frame 34. Areas 37-1 and 37-2 are the target areas for the pedicle screws, as discussed above.

[0048] FIGURE 4 shows cannulas 41 and 42 which could be identical, if desired. Cannula 41 includes opening 401 to allow for lateral adjustment of the distal end of brace 90. On cannula 42, opening 402 can be adjusted downward from that of cannula 41 (because of the arc of brace 90) so as to more precisely capture and retain proximal end 91 of brace 90. Also, as will be seen, the shape of opening 402 on cannula 42 can be adopted to receive the shape of end 91 of brace 90, and lower opening 401 eliminated, if desired.

[0049] FIGURE 5A shows pedicle screw 51, and brace rod adjustment assembly 52. Assembly 52 acts as a hinge for brace 90 positioned within cannula 41. Screw portion 51 is extended out from the base of the connection in an in-line orientation with brace 90. By the application of torque to proximal end 91 of brace 90 by a screwdriver (or wrench), as discussed above, and or as shown in FIGURE 11, screw 51 can be turned so that it can be screwed into the bone as desired. Note that assembly 52 has two openings 520 and 521 which, as will be seen, allow brace 90 to pivot.

[0050] Screw 51 is connected to assembly 52 as will be described herein. This combination is attached to the distal end of cannula (extension) 41 by, for example,

constructing flexible fingers at the distal end of cannula 41 and constructing on the inside of these fingers protrusions in the form, for example, of small pyramids. These pyramids then fit into a tight mating relationship with mating structures constructed on the parity of assembly 52. When it is desired to release cannula 41 from assembly 52, upward pressure and perhaps a tap is applied to the ring at the proximal end of cannula 41. That upward force causes the fingers to fly outward. Thereby releasing the above-described mated structures. This same arrangement is used to assemble and release cannula 42 from assembly 62 (FIGURE 6A)

[0051] FIGURE 5B is a cross-section taken through line 5B-5B of FIGURE 5A and shows screw 51 attached to brace 90 via assembly 52. Brace 90 is shown curved to approximate the spinal curvature. The length of brace 90 is selected to show the distance between the respective anchors. For the L5-L4 level this distance is approximately 35 mm to 45 mm.

[0052] FIGURE 5C shows screw 51 having neck 53 and head 54. Screw 51 also has recess area 55 designed for mating with end 92 of brace 90. This mating can be a slot or other flat configuration or any means of connecting two structures together so that force (in this embodiment the force is torque) can be delivered from one to another. Brace 90 will, when desired, lift upward so as to unmate end 92 from flat 55 so that brace 90 can then pivot with respect to assembly 52. Bearings 501 positioned in slots 93 of brace 90 facilitate such pivoting. Slots 93 serve to limit the in-line and lateral distance brace 90 can move. Bearings 501 also serve as a pivot point for brace 90 and to prevent brace 90 from turning.

[0053] Assembly 52 allows brace 90 to move from the in-line position to a rotated position while also accommodating the lateral motion of brace 90. This lateral motion accommodates different lateral distances between anchors. Assembly 52 can be constructed in different ways and from different materials as desired, for example, as shown in U.S. Patent 5,672,176 hereby incorporated by reference herein. When brace 90 is repositioned to approximately a 90° angle and a set screw (not shown) is in place within threads 506, pressure is applied downward on the side of brace 90. This action, in turn, applies pressure on clamp 502, forcing wedge 503 against head 54 of screw 51. This then locks the polyaxial mechanism in place and prevents brace 90 from further

movement with respect to screw 51. This clamping action also maintains the relative angular position between brace 90 and screw 51. Spring band 505 snaps between a groove in clamp 502 and a groove in shell 504 holding assembly 52 together. Note that assembly 52 can be separate from screw 51 as shown or can be constructed integral thereto. Also note that the polyaxial motion described is not necessary and can be eliminated, if desired.

[0054] FIGURE 6A shows cannula 42 having slot 403, with opening 402 positioned to receive end 91 of brace 90. Once end 91 is captured within slot 402, end 91 passes down inside cannula 42 carrying brace 90 down slot 403 toward assembly 62. Slot 620 in assembly 62 allows brace 90 to enter assembly 62.

[0055] FIGURE 6B is a cross-section taken along lines 6B-6B of FIGURE 6A, and shows assembly 62 with receptacle 66. Receptacle 66 is designed, in one embodiment, to snap together with end 91 of brace 90. This snap-action provides positive feed back to the surgeon, either by feel or audibly, or both. This tactile (or audible) feed back is caused, for example by end 91 passing into receptacle 66. In one embodiment, a force fit could be achieved between end 91 and receptacle 66 by making the inner circumference of the outer rim of receptacle 66 smaller than the diameter of end 91. Mating can be facilitated by cutting small grooves or slots in receptacle 66 to allow receptacle 66 to expand around end 91 for a locking fit. This expansion occurs as end 91 enters into receptacle 66. As the mating occurs, end 92 of brace 90 (FIGURE 7A) is free to move laterally with respect to anchor 51 since brace 90 is held in place (as discussed above) by bearings 501 riding in slots 93 (FIGURE 7C).

[0056] FIGURE 6C shows an expanded view of assembly 62 mounted to head 64 of screw 61. Receptacle 65 accepts a wrench or screw driver from the surgeon for inserting screw 61 into the bone and is accessible through the base of receptacle 66. Clamp 602 acts on wedge 603 to apply force on head 64 of screw 61. Until tightened fully by a set screw positioned within threads 606, assembly 62 is free to rotate polyaxially around head 64 of anchor 61. This polyaxial movement can, if desired, be eliminated.

[0057] FIGURE 7A shows the brace/screw assembly with brace 90 repositioned approximately 90° with respect to screw 51. Screw 51 would be embedded in a bony structure (or other hard structure), not shown in FIGURE 7A. In a particular application, the exact rotation will depend upon many factors, including the angle between anchors and the angle the respective anchors make with respect to the bone in which they are imbedded.

[0058] FIGURE 7B shows a cross-section taken along line 7B-7B of FIGURE 7A. As shown, brace 90 is rotated approximately 90° with respect to assembly 52. End 92 of brace 90 has been disengaged from mating structure 55 on head 54 of screw 51. In FIGURE 7B, set screw 220 is shown about to press down on brace 90 to compress brace 90 to screw head 54, as previously discussed.

[0059] FIGURE 7C is a cross-section taken through line 7C-7C of FIGURE 7A and again shows brace 90 rotated 90° with respect to screw 51. Lateral movement of brace 90 (in and out of the page in FIGURE 7C and left and right in FIGURE 7B) is facilitated by bearings 501 riding in grooves 93 of brace 90 and acting both as a fulcrum and as lateral limitation. All such movement is inhibited when set screw 220 presses down on brace 90. Wing 511 on clamp 503 prevents clamp 503 from upward movement.

[0060] FIGURE 8A shows the receptacle/screw assembly with brace 90 positioned in its capture mode with respect to assembly 62. Assembly 62 is, in turn, mounted on head 64 of screw 61. Screw 61 would be embedded in a second bony structure (on other hard structure) not shown in FIGURE 8A.

[0061] FIGURE 8B shows a cross-section taken along line 8B-8B of FIGURE 8A. End 91 of brace 90 is captured by receptacle 66. Set screw 220 is shown applying downward pressure on brace 90 in order to lock brace 90 to screw head 64 as previously discussed. The inner geometry of receptacle 66 is keyed to match the proximal end of brace 90.

[0062] FIGURE 8C shows a cross-section taken along line 8C-8C of FIGURE 8A. End 91 of brace 90 is shown mated with receptacle 66 and locked tight by set screw 220. Once set screw 220 presses down on brace 90, hinge assembly 62 clamps

against head 64 of screw 61 to prevent further movement of brace 90 with respect to screw 61. Area 610 is created in assembly 62 such that receptacle 66 can expand as brace end 91 passes into the receptacle. Wing 611 on wedge 603 prevents wedge 603 from moving upward.

[0063] FIGURE 9 shows one embodiment of brace 90 with distal end 92 and proximal end 91. Slot 93 is longer than actually necessary to allow for lateral movement of brace 90 during the seating process so as to allow for different distances between anchors. As discussed, distal end 92 can have any shape required for mating with head 54 of screw 51 for the purpose of force transfer. Also note that proximal end 91 has a ball (or partial ball) shape for capture by slot 402 of cannula 42. End 91 can have any shape, provided such shape is adapted for capture by cannula 42.

[0064] FIGURE 10 shows a single level brace system 1000 having brace 90 with its distal end 92 clamped tightly with respect to screw 51 (a first anchor) and its proximal end 91 clamped tightly with respect to screw 61 (a second anchor). Each of these anchors is firmly supported in a respective bony structure (not shown in FIGURE 10) of a patient. Note that brace 90 is slightly curved to, at least partially, adjust for the spine curvature. Also note that the respective anchors are not necessarily parallel to each other but each has assumed an angle necessary for proper placement in the pedicle (or other bony area) of the respective vertebra. While the brace has been shown with respect to the L4 and L5 vertebrae, the system, method, and device discussed herein are not so limited and can be used between any bony or other hard portions that must be supported, including single level or multilevel.

[0065] For bracing two or more levels, one option is to skip one or more vertebral levels onto the anchor, another option is to use a "pass-through" anchor assembly on the skipped vertebral level(s). The pass-through assembly can be adapted for locking to the brace on the portion of the brace passing through the middle assemblies. Another option would be to have a dual headed anchor on the center vertebra which accepts braces, one brace from each of the other surrounding levels.

[0066] Although the present invention and its advantages have been described in detail, it should be understood that various changes, substitutions and

alterations can be made herein without departing from the invention as defined by the appended claims. Moreover, the scope of the present application is not intended to be limited to the particular embodiments of the process, machine, manufacture, composition of matter, means, methods and steps described in the specification. As one will readily appreciate from the disclosure, processes, machines, manufacture, compositions of matter, means, methods, or steps, presently existing or later to be developed that perform substantially the same function or achieve substantially the same result as the corresponding embodiments described herein may be utilized. Accordingly, the appended claims are intended to include within their scope such processes, machines, manufacture, compositions of matter, means, methods, or steps.

CLAIMS

What is claimed is:

1. A device for immobilizing two structures, said device comprising:

a first anchor for becoming secured with respect to a first structure; and

a brace having a distal end pivotally mated with a proximal end of said first anchor, said pivotal mating occurring before said first anchor is secured with said first structure.

2. The device of claim 1 wherein said distal end of said brace is adapted for transferring torque and compressive force from said brace to said first anchor.

3. The device of claim 1 wherein said brace comprises:

a proximal end, said proximal end adapted for locking with a mating receptacle attached to the proximal end of a second anchor secured in a second structure spaced apart from said first structure, said locking occurring when said distal end of said brace pivots with respect to said proximal end of said first anchor, said pivoting occurring while said distal end of said brace remains pivotally mated with said proximal end of said first anchor.

4. The device of claim 3 wherein said receptacle allows for polyaxial rotation with respect to said second anchor.

5. The device of claim 3 wherein said receptacle is a force fit with respect to said proximal end of said brace.

6. The device of claim 3 wherein said receptacle provides positive feedback when said proximal end of said brace is properly mated with said receptacle.

7. The device of claim 1 further comprising:

a hinge attached to a proximal end of said first anchor for facilitating said pivotal mating.

8. The device of claim 7 wherein said hinge allows for polyaxial rotation with respect to said first anchor.

9. The device of claim 1 wherein said proximal end of said brace is further adapted to accept torque applied thereto.

10. The device of claim 1 wherein said structures are vertebrae and wherein said anchors are screws for placement in the pedicle of said vertebrae.

11. A system for spinal vertebrae immobilization comprising:

a first cannula;

a first pedicle screw for implantation in a first vertebra; said implantation occurring by connecting said first pedicle screw to a distal end of said first cannula;

a brace having a first end for pivotally mating with a proximal end of said first pedicle screw while said brace is attached to a said proximal end of said first pedicle screw, said brace positioned within said first cannula while said first pedicle screw is being implanted in said first vertebra; and

said first cannula having at least one opening therein for allowing a mated brace to pivot with respect to said first pedicle screw.

12. The system of claim 11 further comprising:

a first mating structure at the distal end of said brace; and

a second mating structure at said proximal end of said first pedicle screw, wherein said first and second mating structures are adapted for power transfer.

13. The system of claim 12 wherein said first pedicle screw is implanted by said power transfer.

14. The system of claim 13 wherein said power transfer is torque transfer.

15. The system of claim 11 further comprising:

a second cannula;

a second pedicle screw for implantation in a second vertebra;

a receptacle attached to a proximal end of said second pedicle screw, said receptacle positioned within said second cannula when said second pedicle screw is implanted in said second vertebra; and

said second cannula having at least one opening therein for allowing said proximal end of said brace to enter said second cannula and mate with said receptacle when said brace pivots with respect to said first pedicle screw.

16. The system of claim 15 wherein said last-mentioned mating causes a distinctive sensory event when said proximal end of said brace is properly positioned with respect to said receptacle.

17. The system of claim 15 wherein said opening in said first and second cannulas allow said cannulas to be removed from said patient after said brace is mated with said receptacle.

18. The system of claim 15 wherein said receptacle is polyaxial with respect to said second pedicle.

19. The system of claim 15 wherein said brace accepts locking devices at each end thereof after said brace is mated to said receptacle, said locking devices preventing further movement of said brace with respect to said screws.

20. A hinge for use with a bone anchor support system, said hinge comprising:

proximal and distal openings in-line from each other forming an in-line passage through said hinge;

said proximal opening comprising a clamp for rotatable attachment to the head of a bone anchor;

said proximal opening adapted to accept the distal end of a brace prior to said bone anchor being secured in a bone, said hinge further comprising a pivot point for capturing an accepted brace so as to allow said accepted brace to pivot with respect to said hinge but not to become released therefrom; and wherein said clamp allows said distal end of an accepted brace to become detachable coupled to said head of an attached anchor for the purpose of force transfer between said brace and said anchor.

21. The hinge of claim 20 wherein the proximal end of said hinge is further adapted to accept a force applying locking structure.

22. The hinge of claim 20 wherein said pivot includes at least one pair of bearings positioned on either side of said in-line passage.

23. A brace for use with a bone anchor support system, said brace comprising:

a curved shank portion slightly longer than the distance between the bones to be supported; said shank comprising:

a first key at its distal end for releasably mating with a head of a first anchor so as to allow torque transfer between said brace and said first anchor; and

a second key at its proximal end for releasably mating with a receptacle at a second one of said anchors.

24. The brace of claim 23 wherein said shank further comprises:

at least one slot longitudinally displaced along said shank in proximity to said distal end, said slot for accepting a fulcrum point affixed to said first anchor so as to allow said brace to pivot around said fulcrum point while still maintaining said shank in controlled spatial relationship with said first anchor.

25. A device for stabilizing first and second bones, said device comprising:

a first bone anchor having an attachment;

means for capturing a brace within said attachment; and

means for supporting a captured brace such that said captured brace can either be in-line with said anchor to assist in fastening said bone anchor to a bone, or positioned to form an angle with said anchor.

26. The device of claim 25 wherein said supporting means comprises:

a pair of bearings displaced on opposite sides of said captured brace, said bearings interfacing with said brace by indentations longitudinally displaced along said brace.

27. The device of claim 26 wherein said brace has a distal end adapted for transmitting force between said brace and said first bone anchor while said brace is in-line with said first bone anchor.

28. The device of claim 27 wherein said transmitted force is torque.

29. The device of claim 26 wherein said brace comprises:

means for engaging a receptacle attached to a second bone anchor spaced apart from said first bone anchor, said device further comprising;

means for polyaxially attaching said receptacle to the head of said second bone anchor; and wherein said receptacle comprises means for engaging with said brace.

30. The device of claim 29 wherein said first and second anchor engagement means comprise:

means for locking said brace and said anchors in a fixed relationship with each other.

31. The method of stabilizing bones, said method comprising:

attaching to a first cannula a first bone anchor having affixed to its proximal end a hinge, said hinge having captured therein the distal end of a bridging rod, said bridging rod engaged with said first bone anchor and extending within said first cannula;

positioning said first cannula in alignment with a first bone location into which said first bone anchor is to be placed; and

applying force through said first cannula to the proximal end of said bridging rod so as to attach said first bone anchor to said first bone at said first bone location.

32. The method of claim 31 further comprising:

attaching to a second cannula a second bone anchor having affixed to its proximal end a receptacle, said receptacle adapted for receiving the proximal end of said bridging rod;

applying force through said second cannula to the proximal end of said second bone anchor so as to attach said second bone anchor to a second bone at a second bone location; and

pivoting said bridging rod at its distal end within said first cannula, wherein said pivoting causes inserting of said proximal end of said bridging rod into said second cannula, said second cannula guiding said proximal end to said receptacle.

33. The method of claim 31 further comprising:

attaching to a second cannula a second bone anchor having affixed to its proximal end a receptacle, said receptacle adapted for receiving the proximal end of said bridging rod;

applying force through said second cannula to the proximal end of said second bone anchor so as to attach said second bone anchor to a second bone at a second bone location;

disengaging said distal end of said bridging rod from said proximal end of said first bone anchor; and

urging said proximal end of said bridging rod out of said first cannula through an opening in a side wall of said first cannula, said urging in a direction toward said second cannula, while said distal end of said bridging rod remains captured by said hinge affixed to said first bone anchor.

34. The method of claim 33 further comprising:

continuing to urge said proximal end of said bridging rod toward said second cannula until said proximal end of said bridging rod enters said second cannula through an opening in a side wall of said second cannula; and

continuing to urge said bridging rod until said proximal end of said bridging rod engages said receptacle.

35. The method of claim 34 wherein said engaging is signaled by sensory feedback.

36. The method of claim 35 wherein said feed back is tactile.

37. The method of claim 34 further comprising:

positioning a first set screw down said first cannula to engage said distal end of said bridging rod; positioning a second set screw down said second cannula to engage said proximal end of said bridging rod; and

tightening said set screws so as to lock said brace, said hinge, said receptacle and said anchors with respect to each other.

38. The method of claim 37 further comprising:

removing said first and second cannulas.

39. The method of claim 38 where said first and second cannulas are positioned through dilators inserted through a common incision in the skin of a patient.

40. The method of claim 39 further comprising:

prior to said disengaging and said urging, removing from said common incision said dilators thereby exposing said first and second cannulas.

41. The method of claim 40 further comprising:

after said first and second cannulas are removed, repairing said common incision.

42. The method of claim 37 wherein at least one of said hinge and said receptacle is polyaxial.

FIG. 1

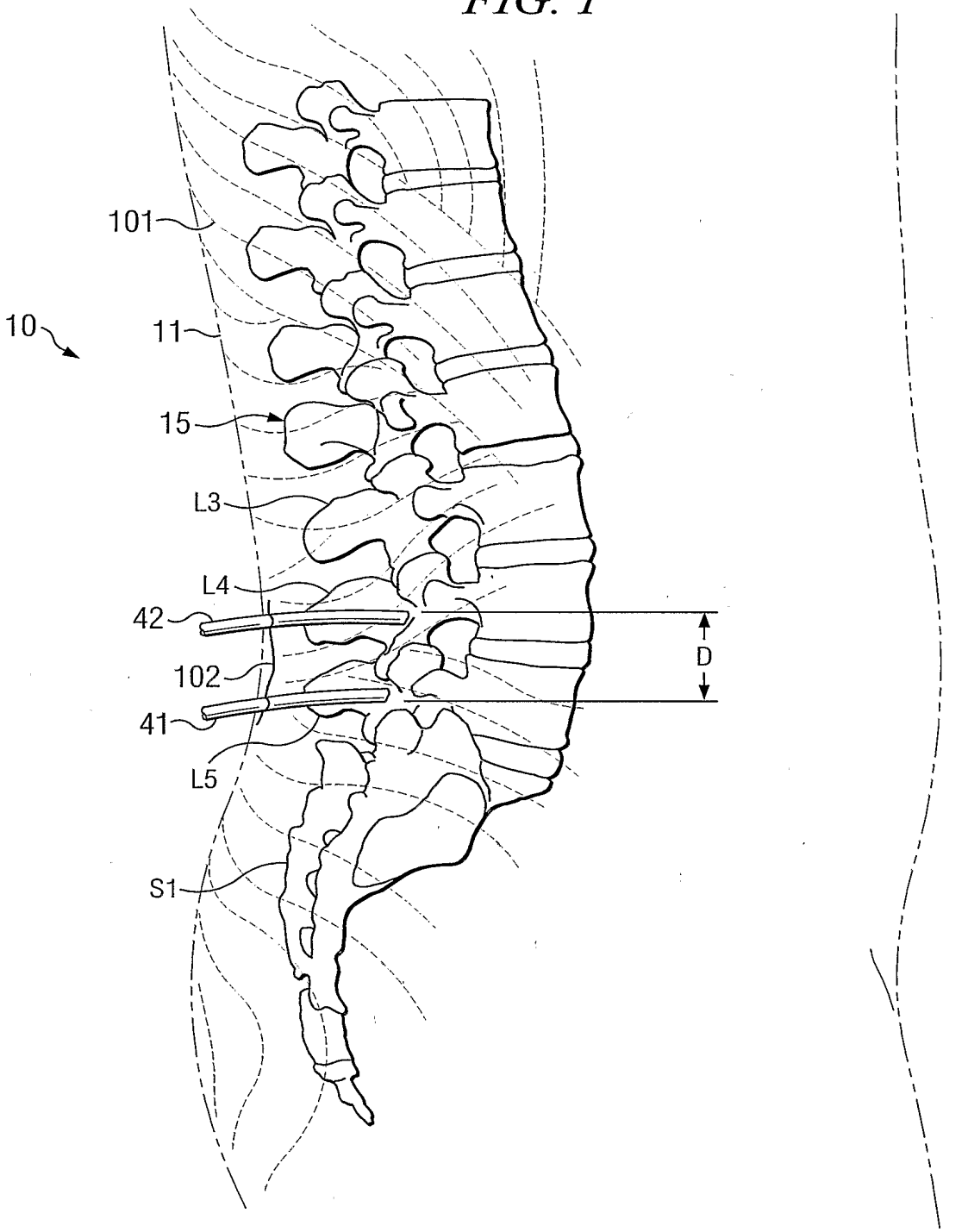


FIG. 2A

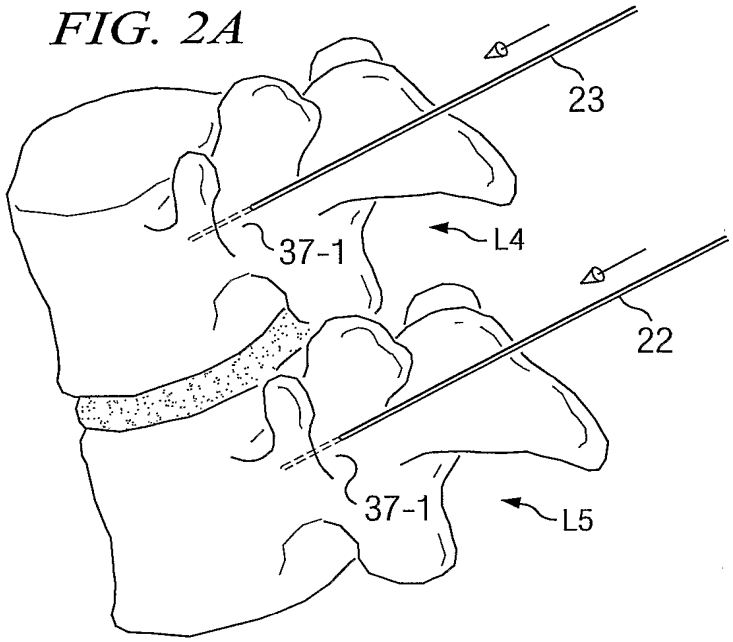


FIG. 2B

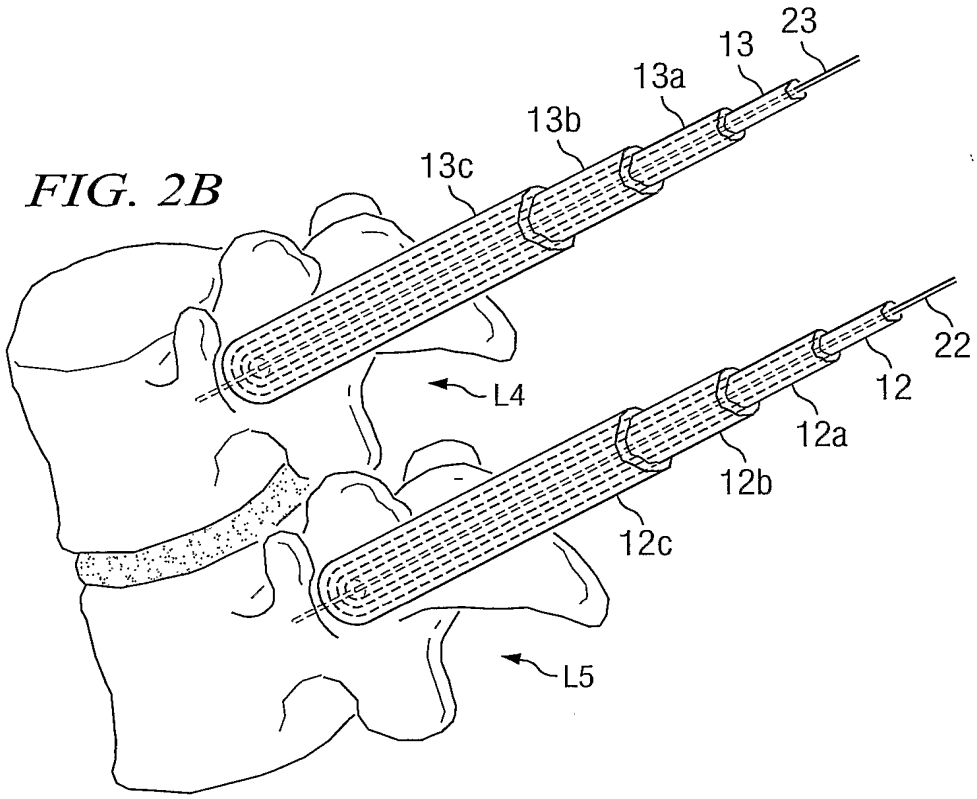
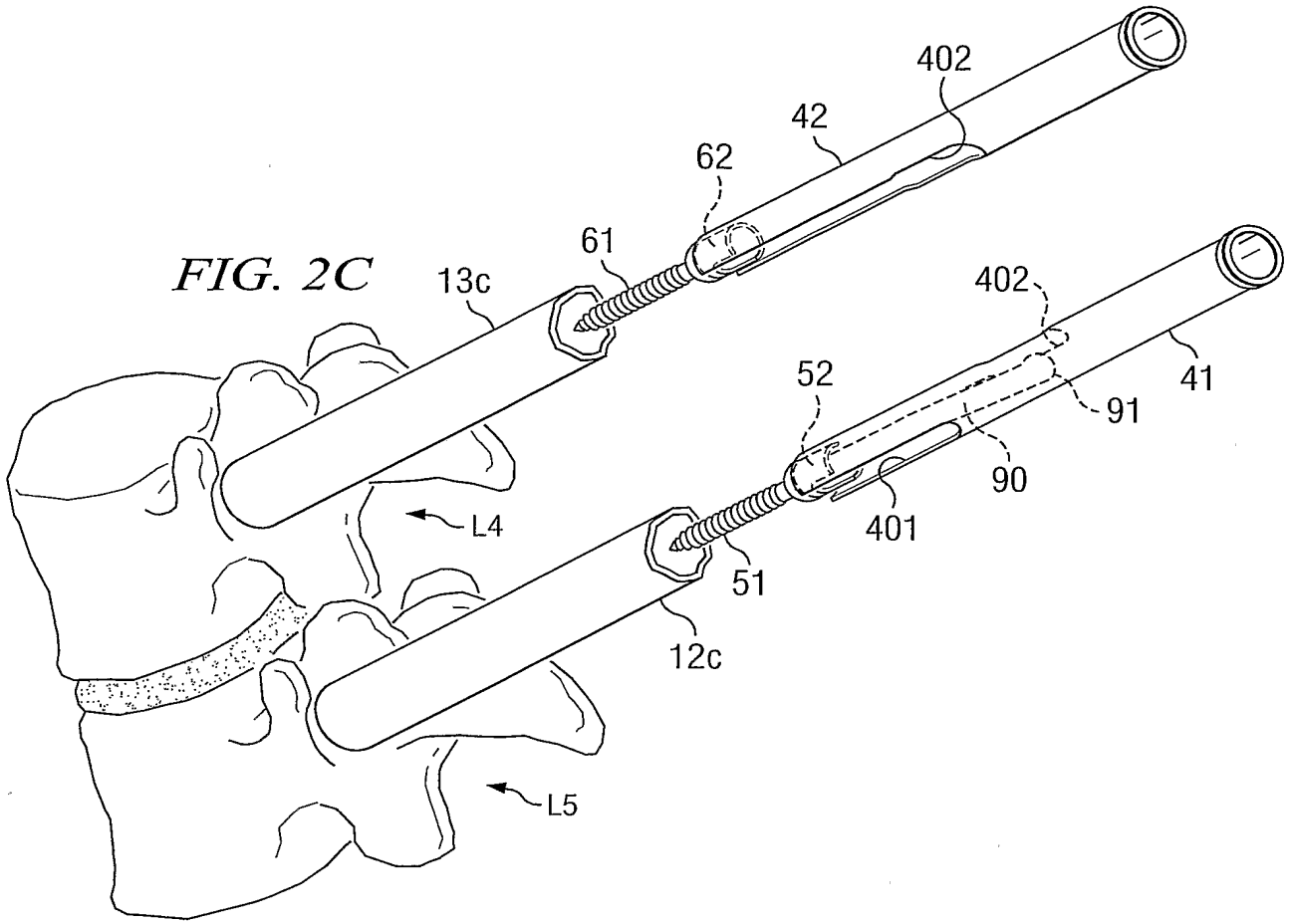


FIG. 2C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L5

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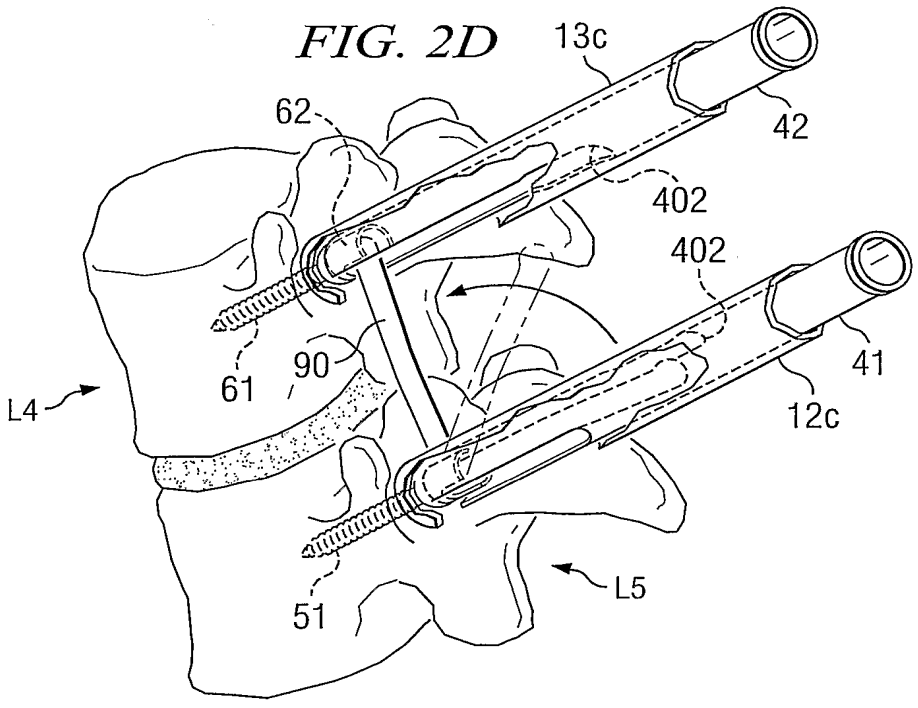
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FIG. 2E

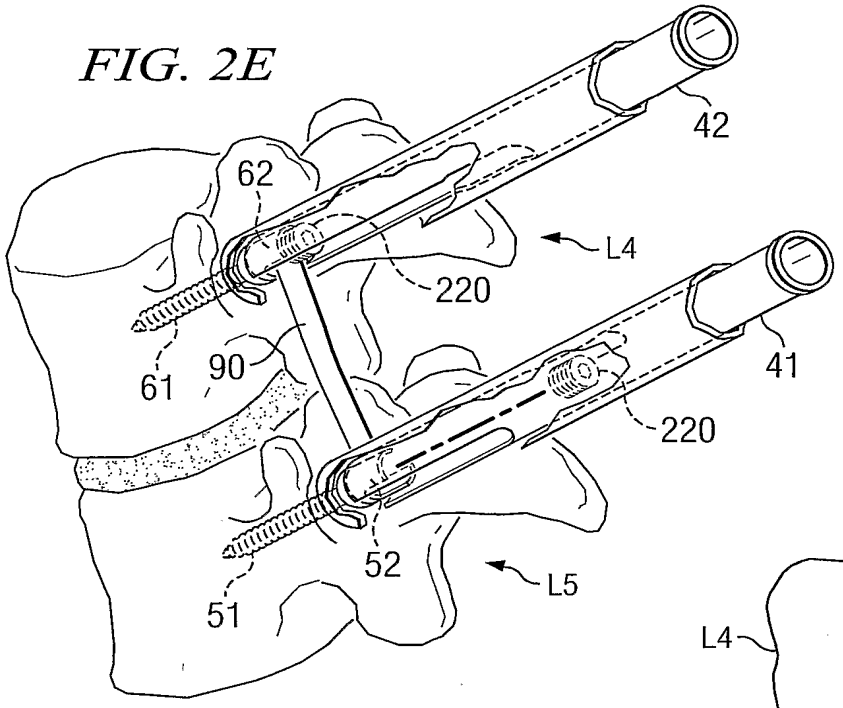

FIG. 3A

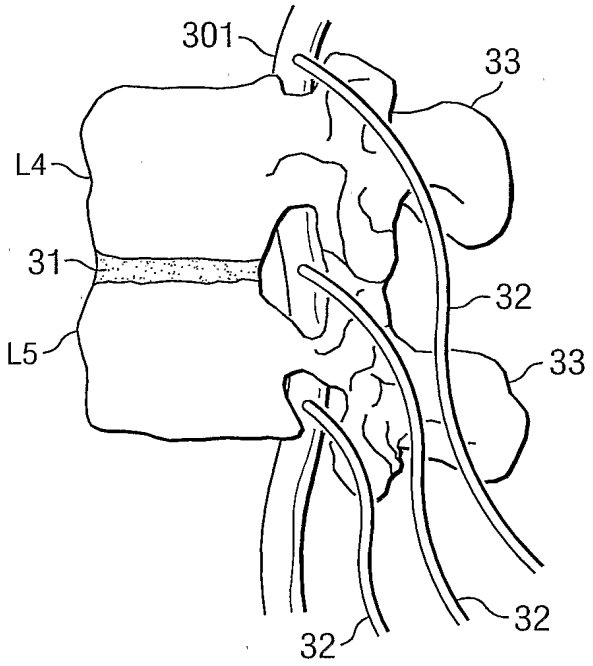

FIG. 2F

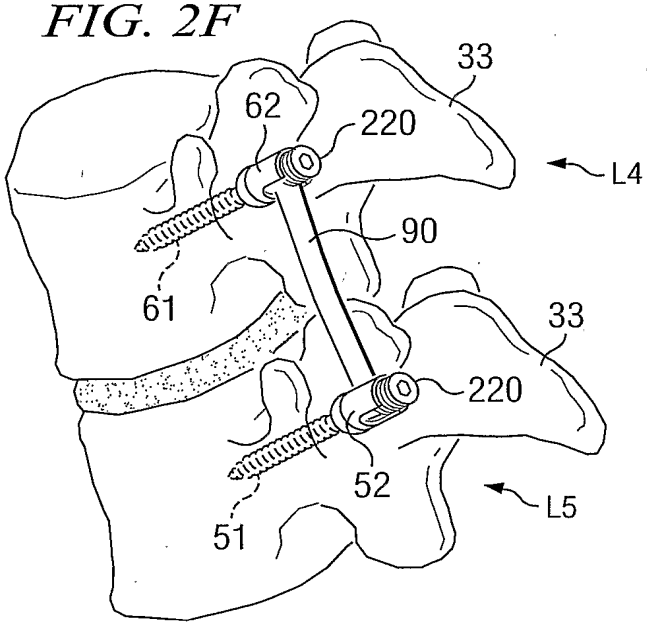

FIG. 3B

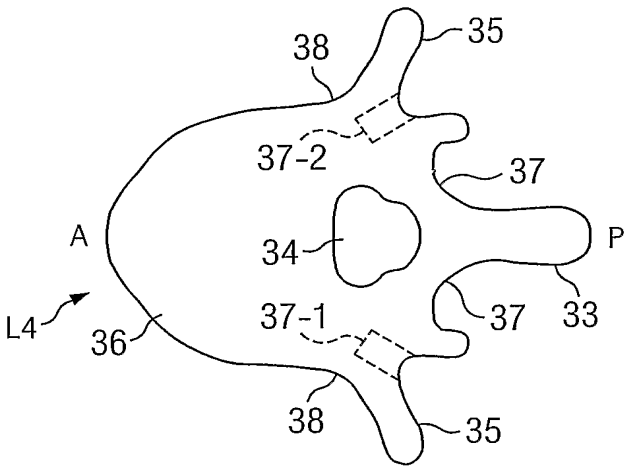

FIG. 4

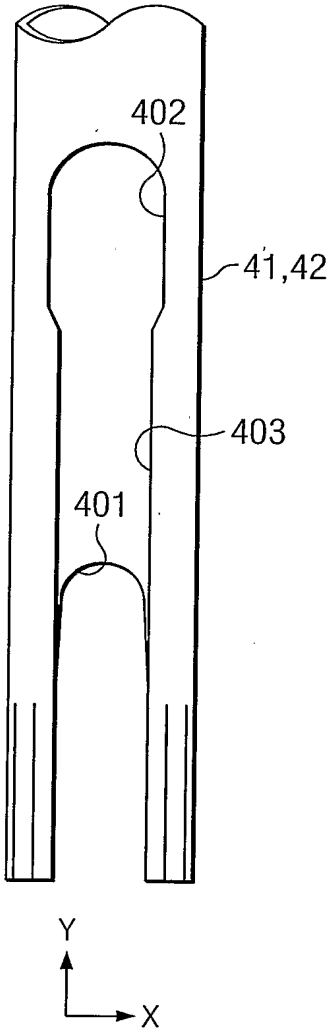

FIG. 5A

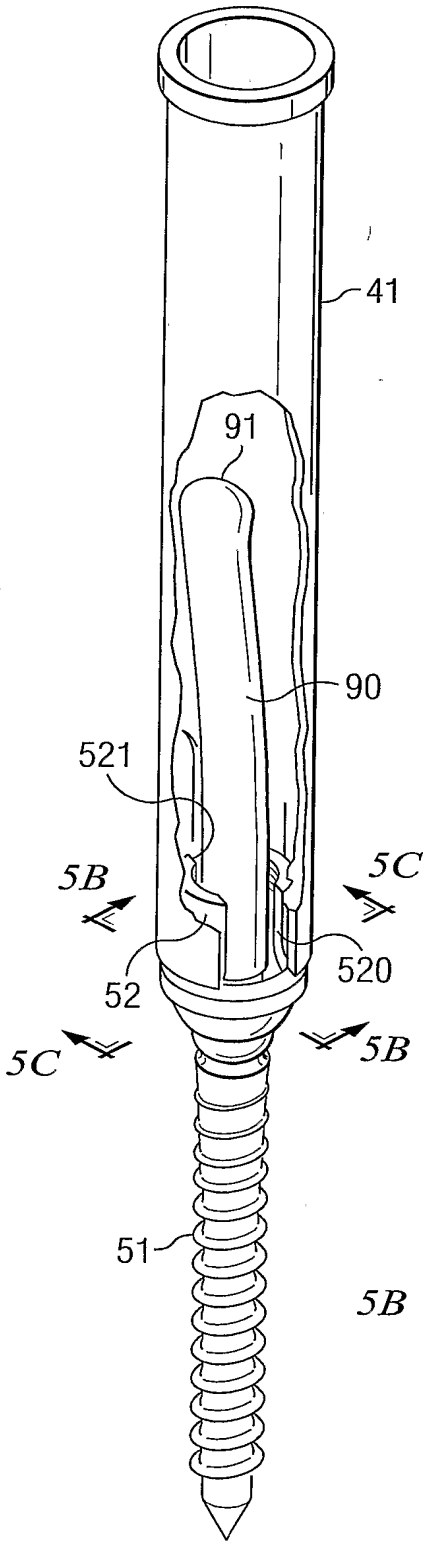

FIG. 6A

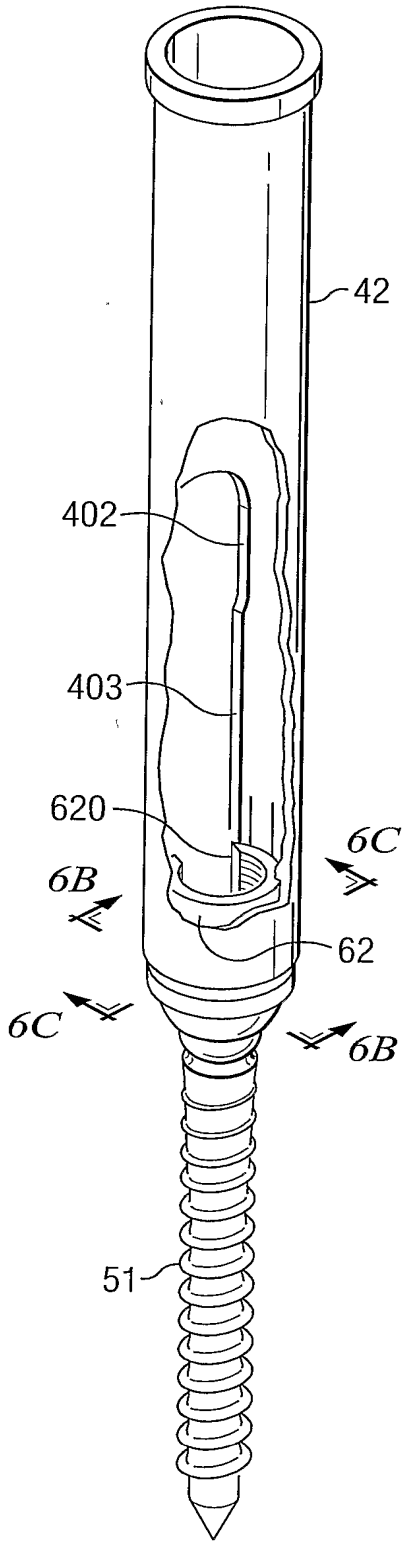

FIG. 5B

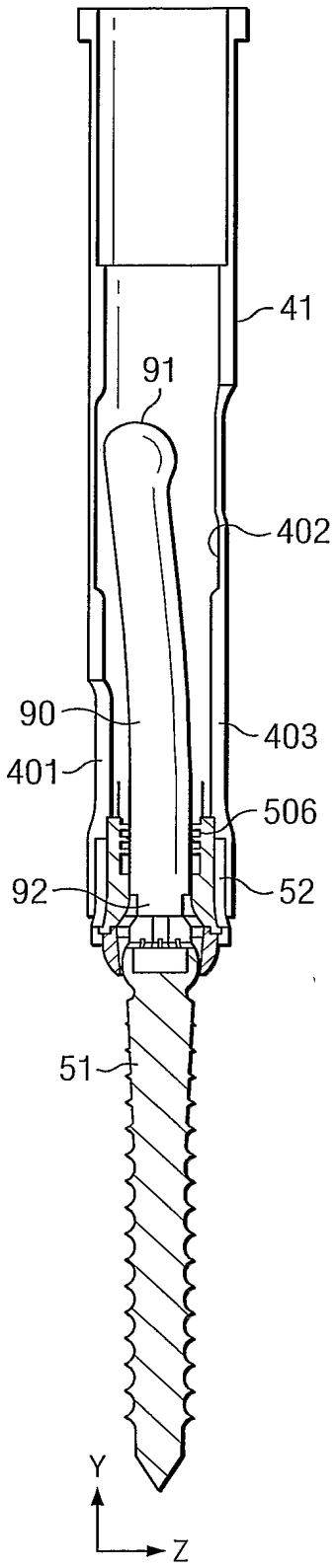

FIG. 6B

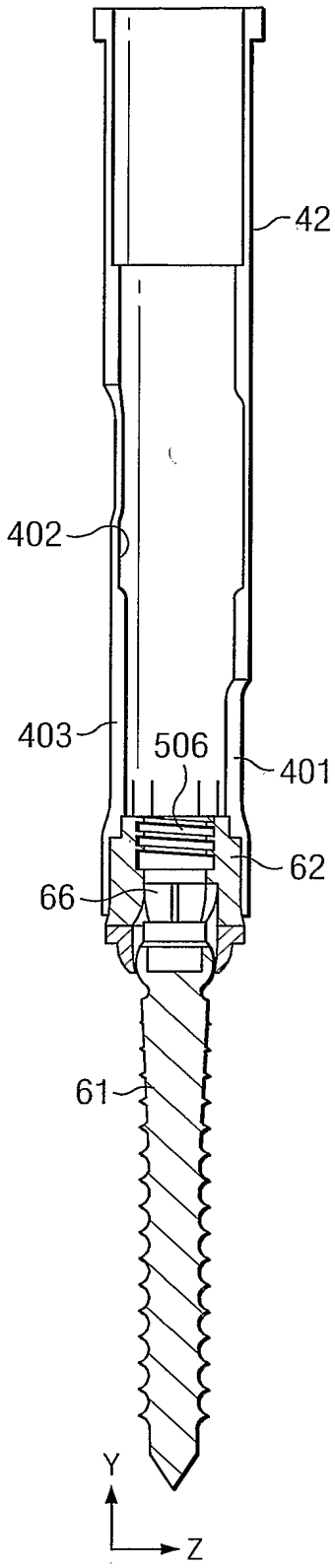

FIG. 11

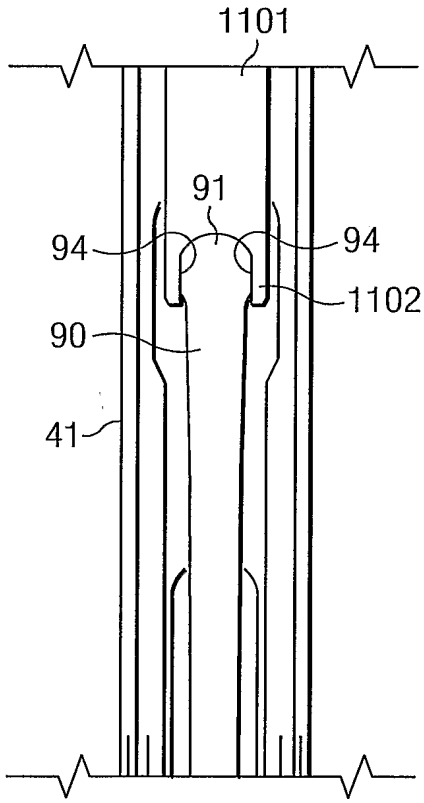

FIG. 5C

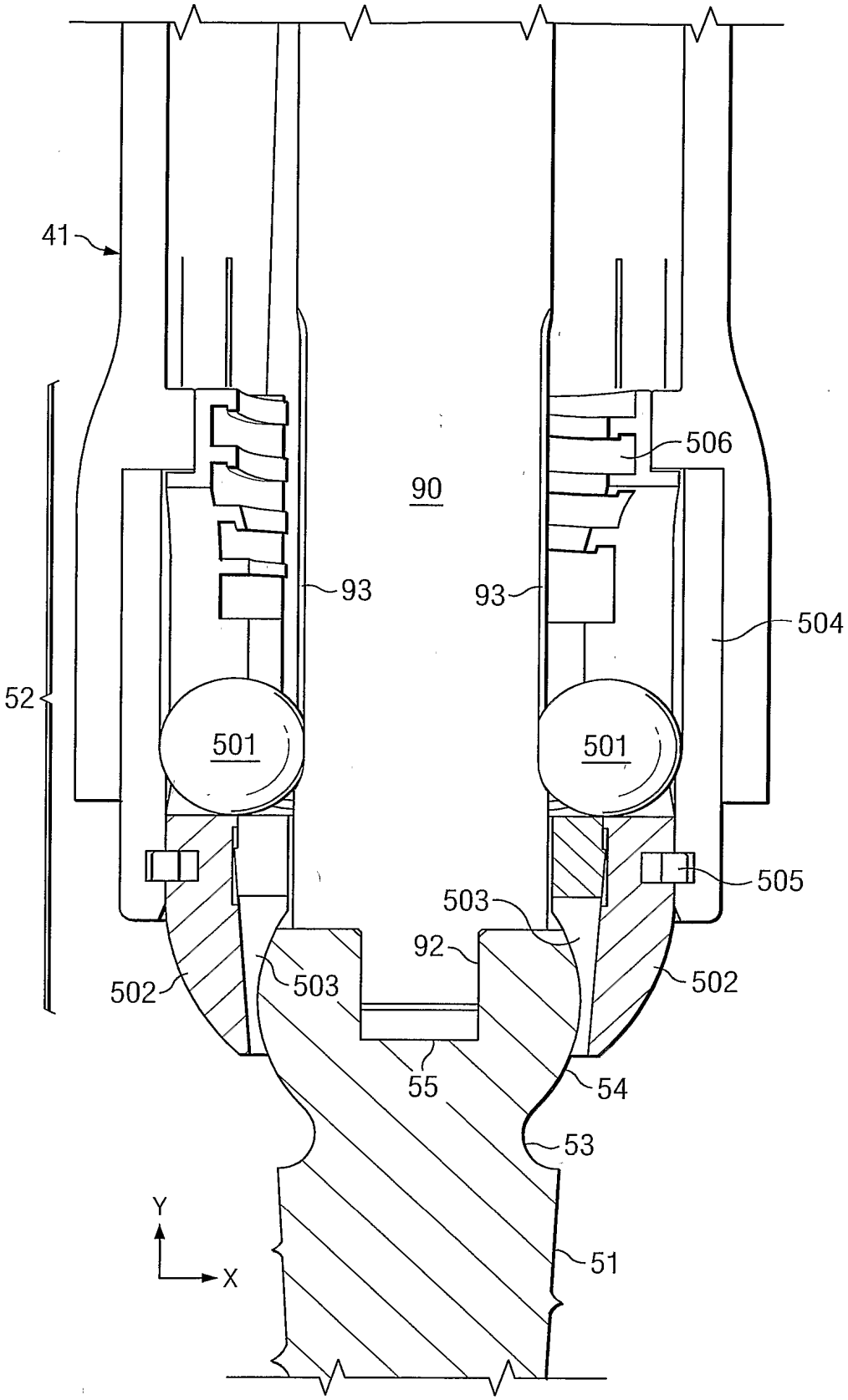

FIG. 6C

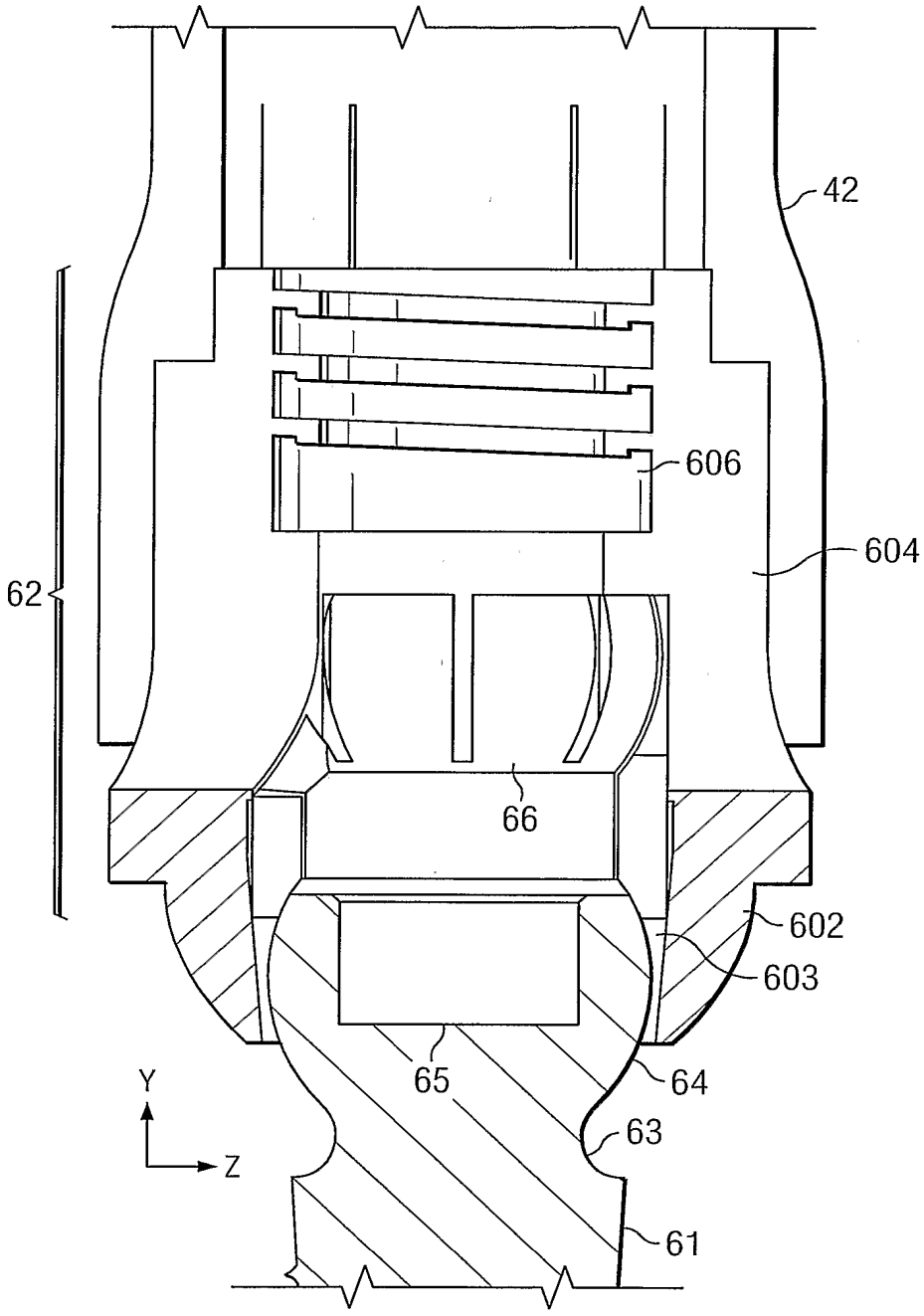

FIG. 7A

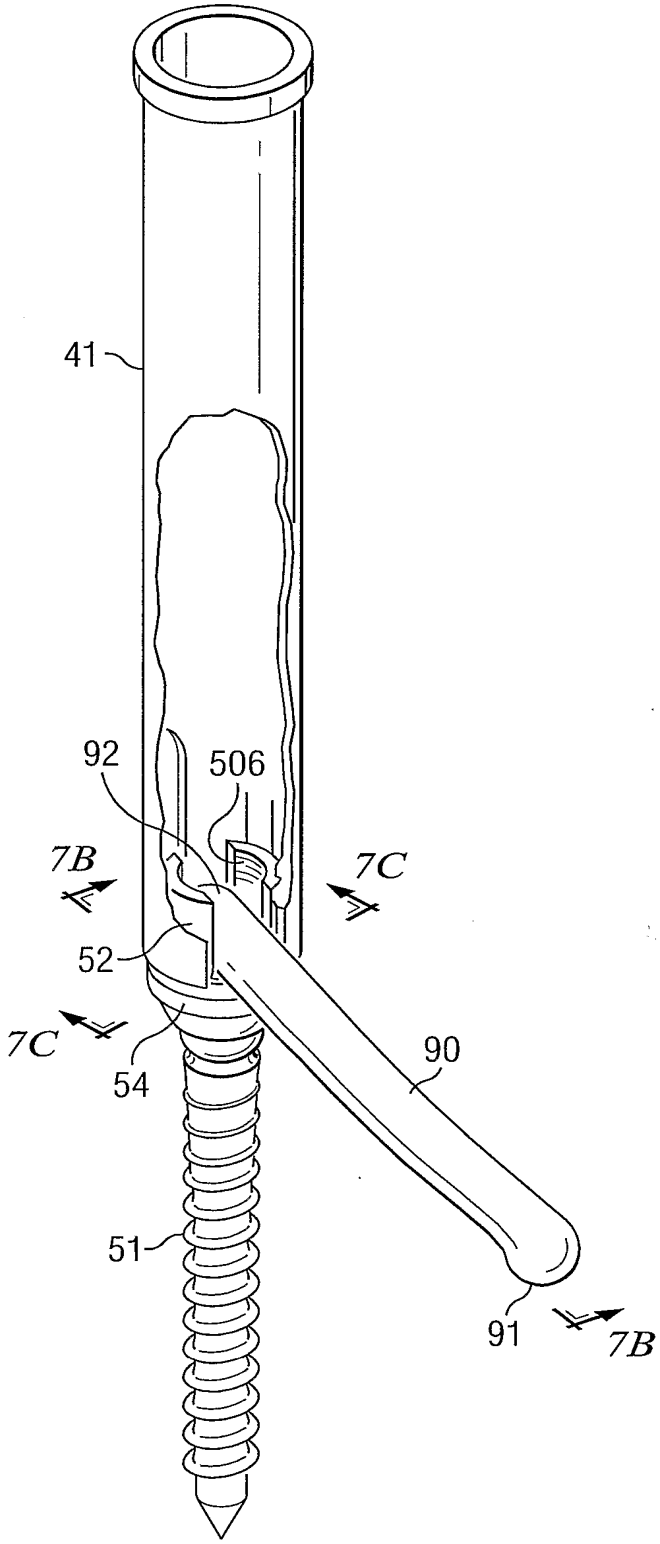
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FIG. 8A

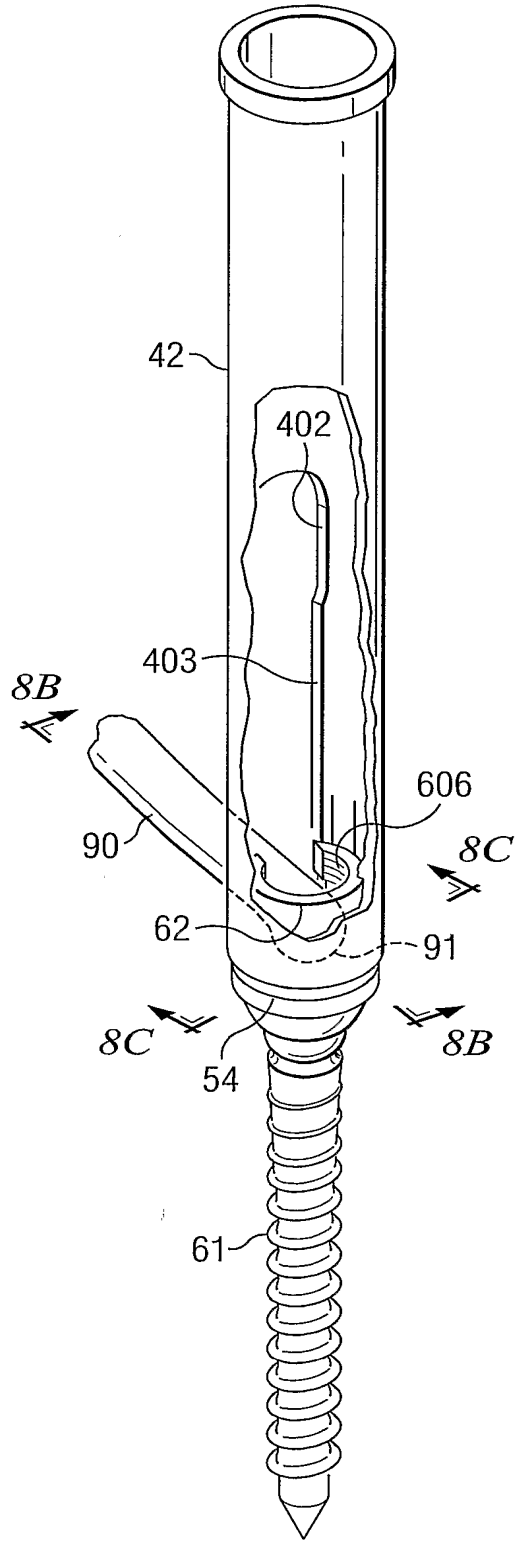
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FIG. 8B

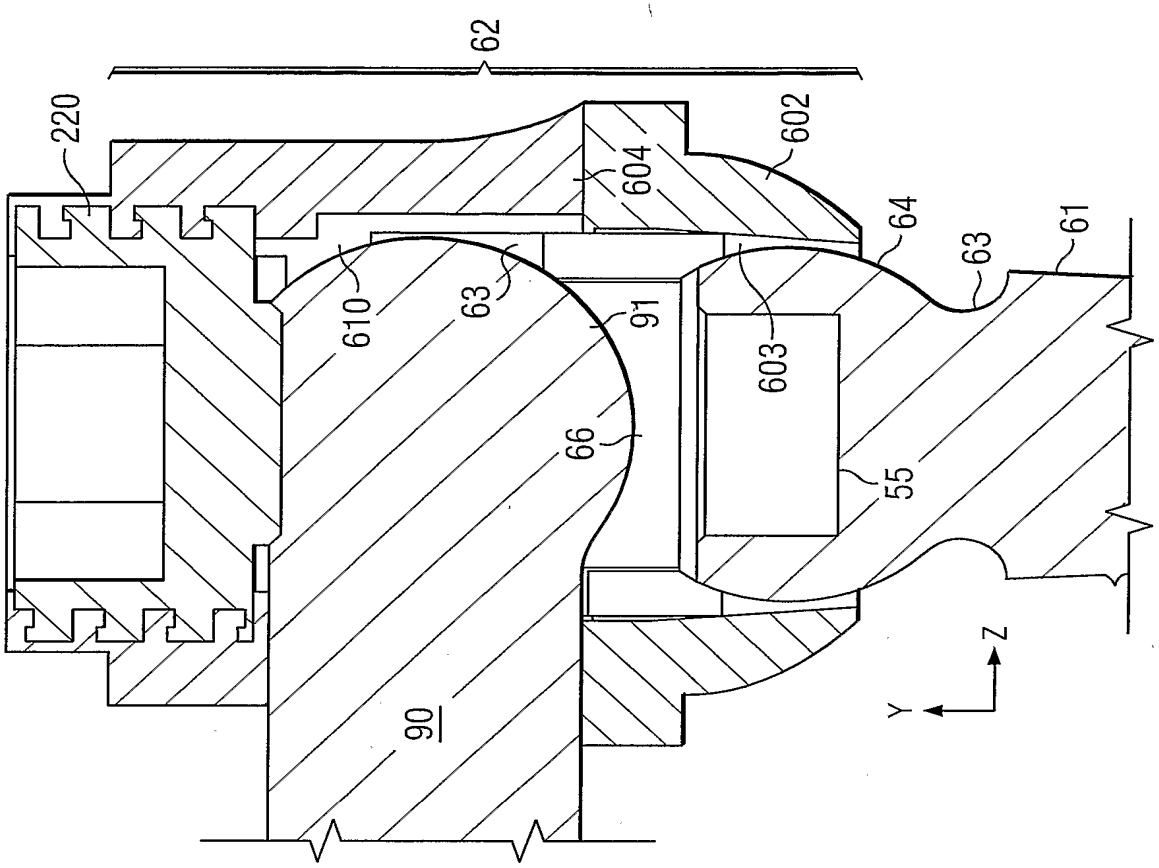
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FIG. 7B

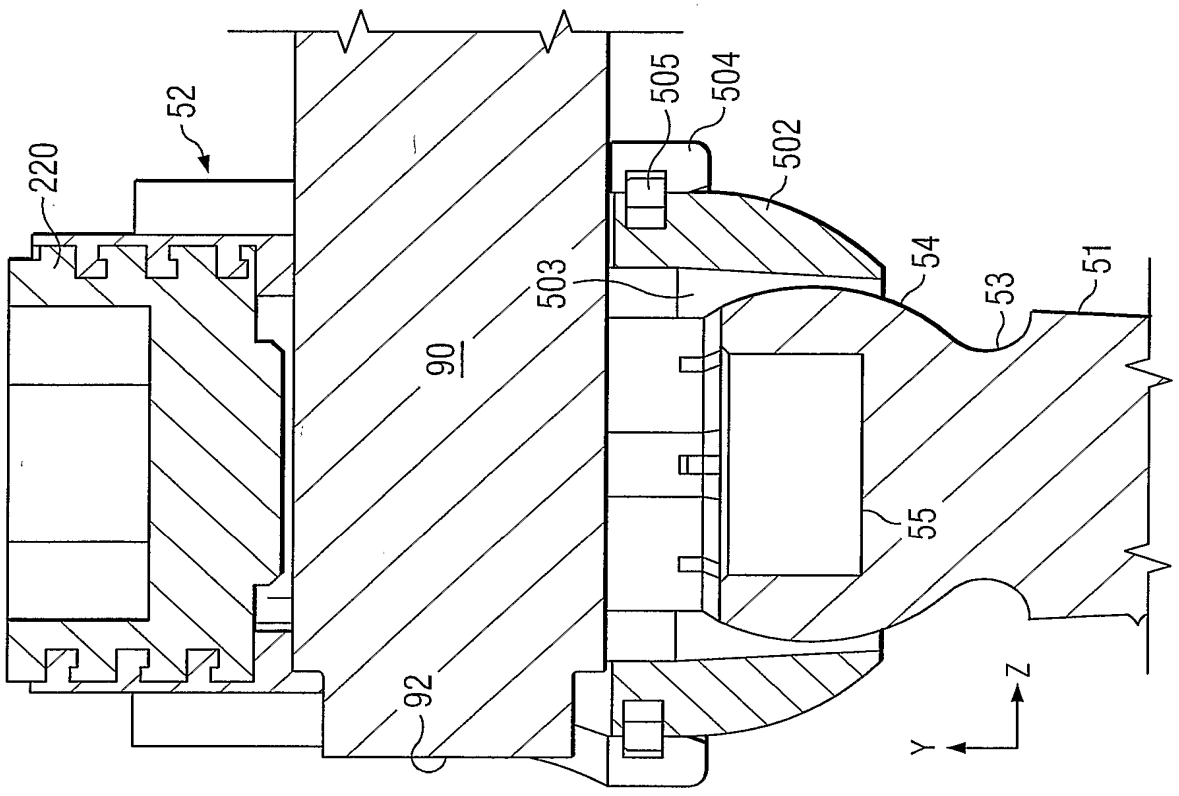
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FIG. 8C

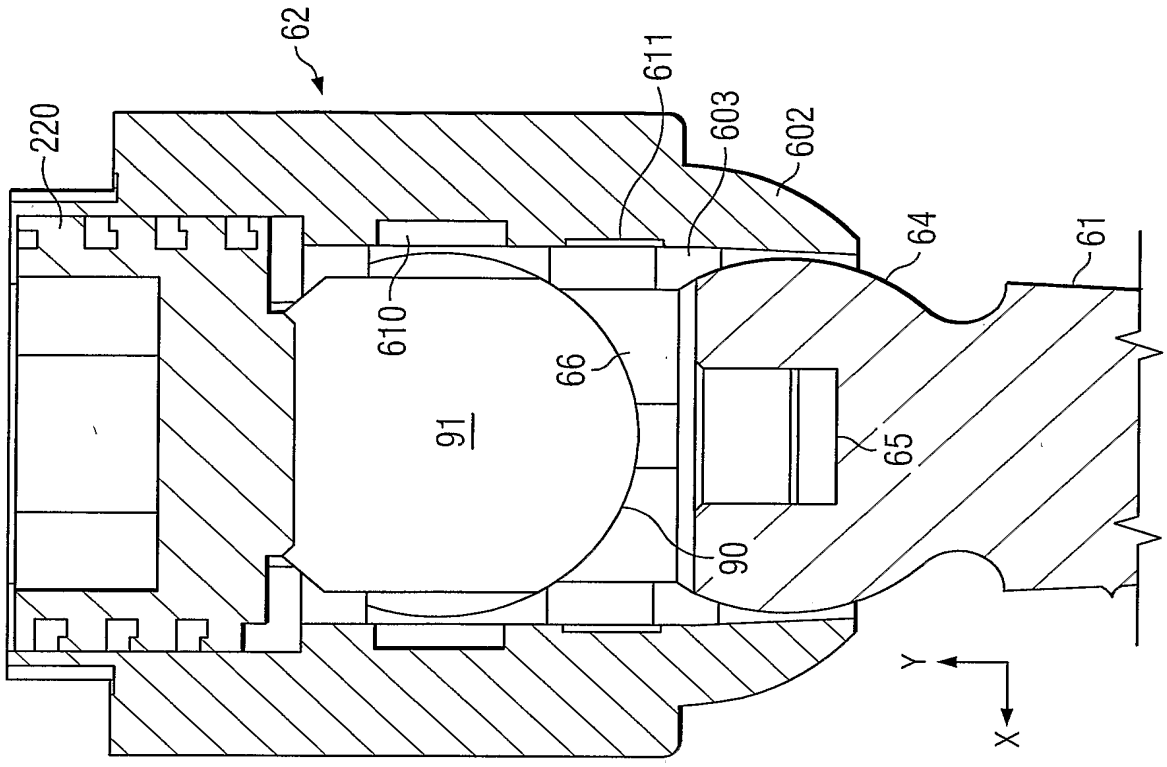
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FIG. 7C

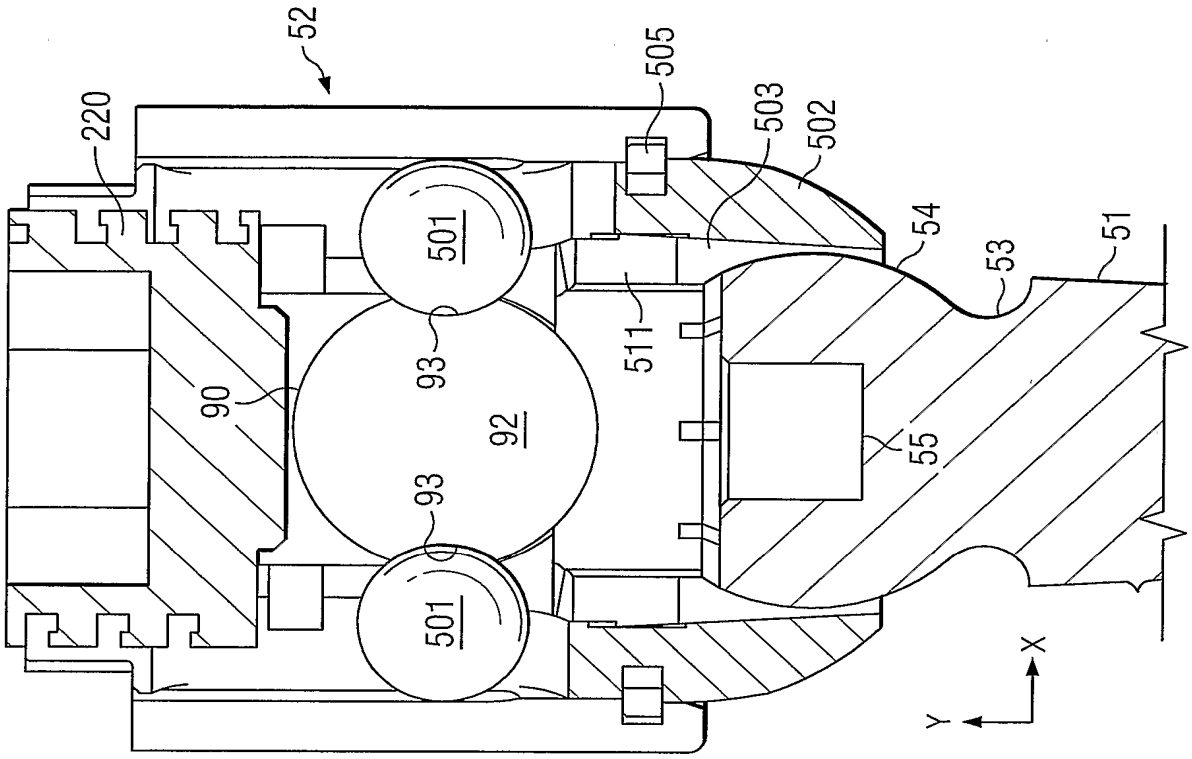
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FIG. 9

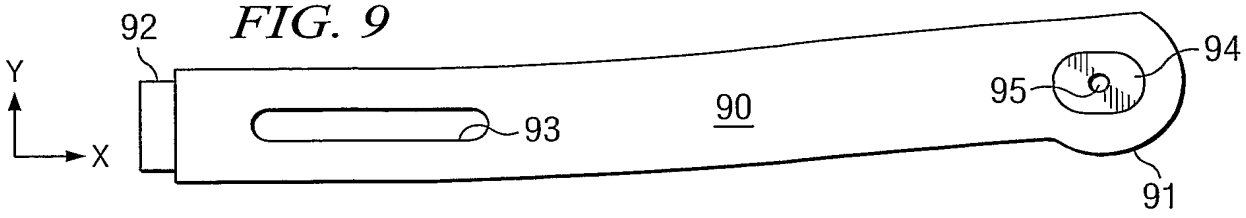

FIG. 10

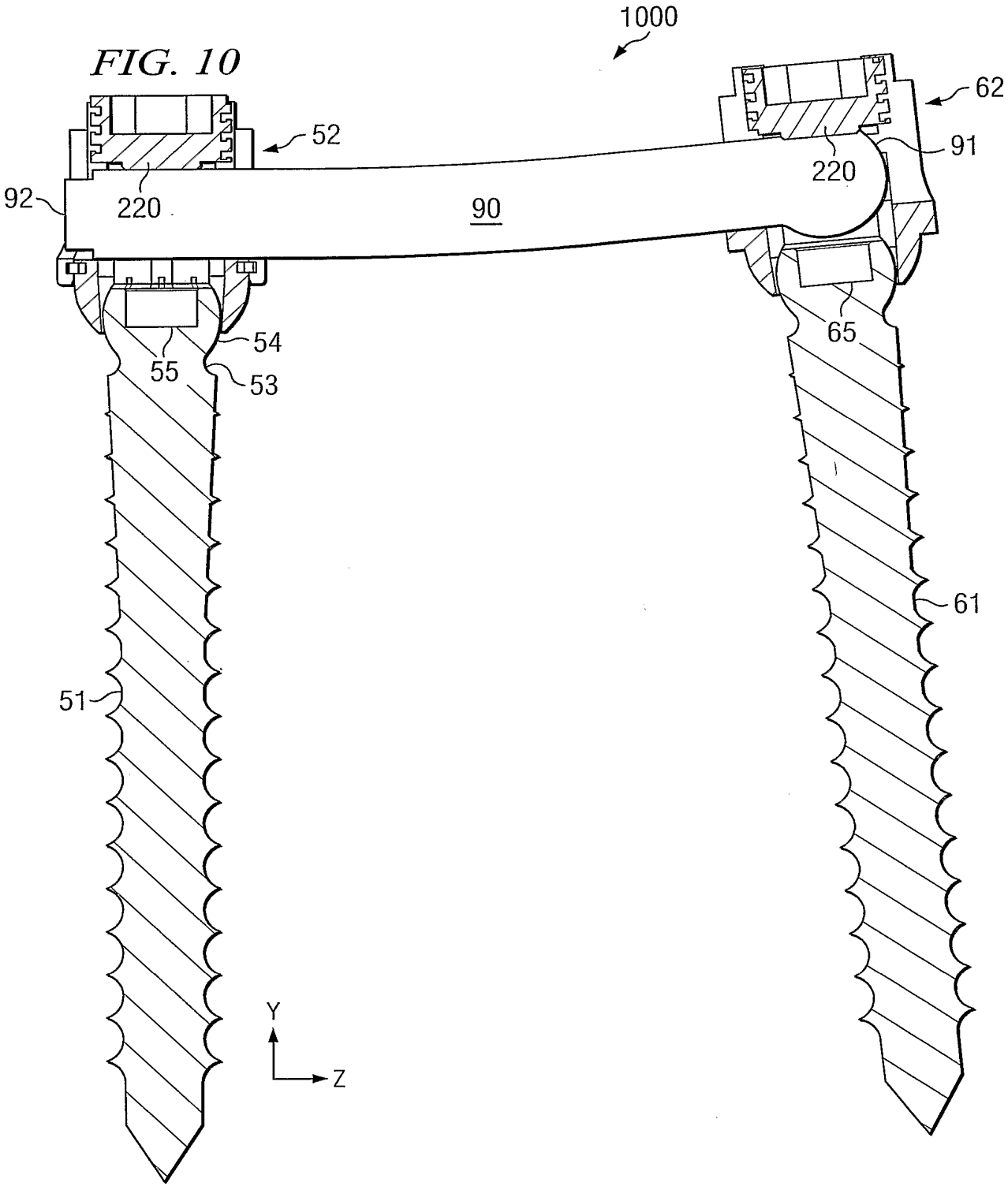

FIG. 12A

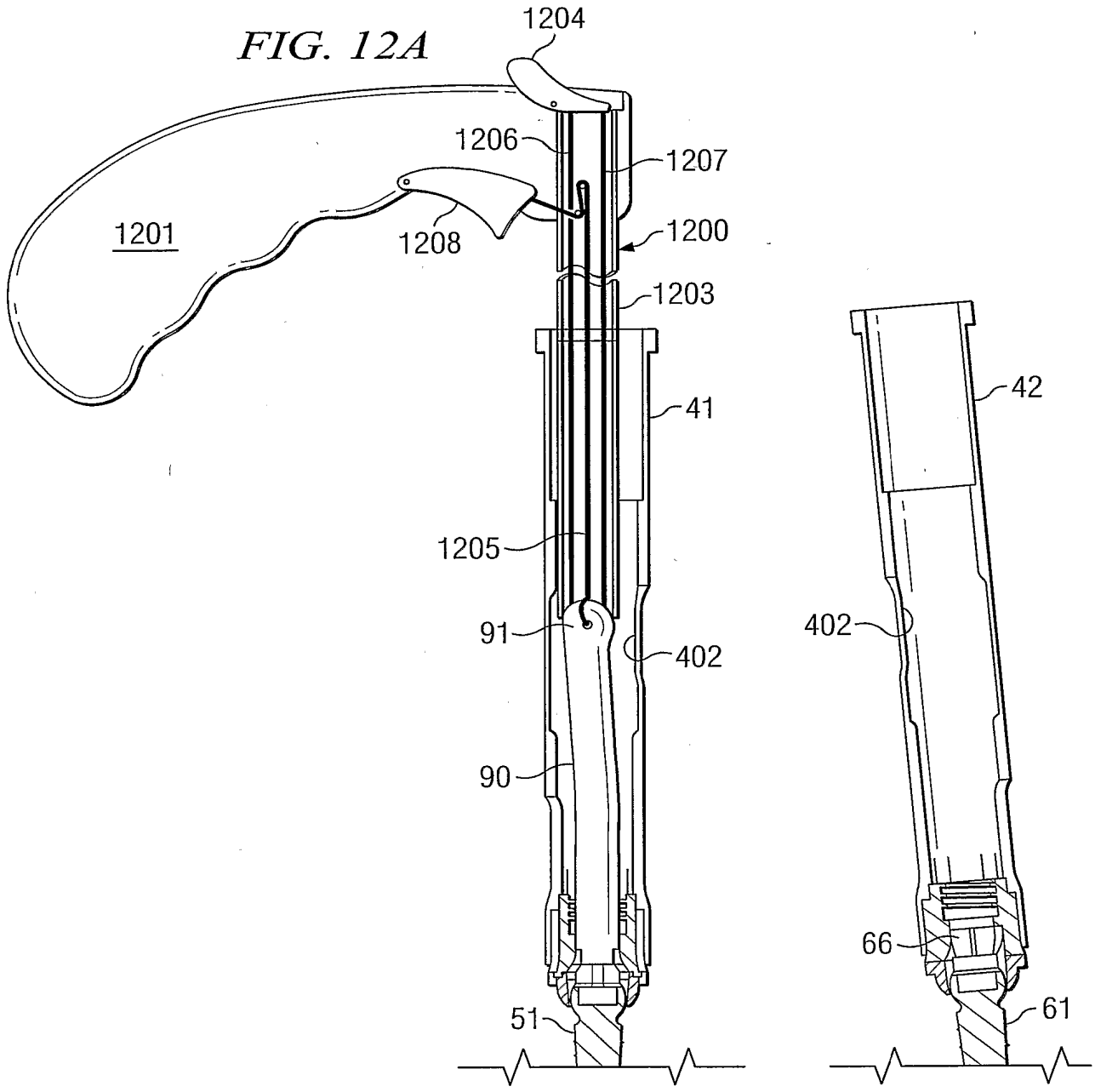
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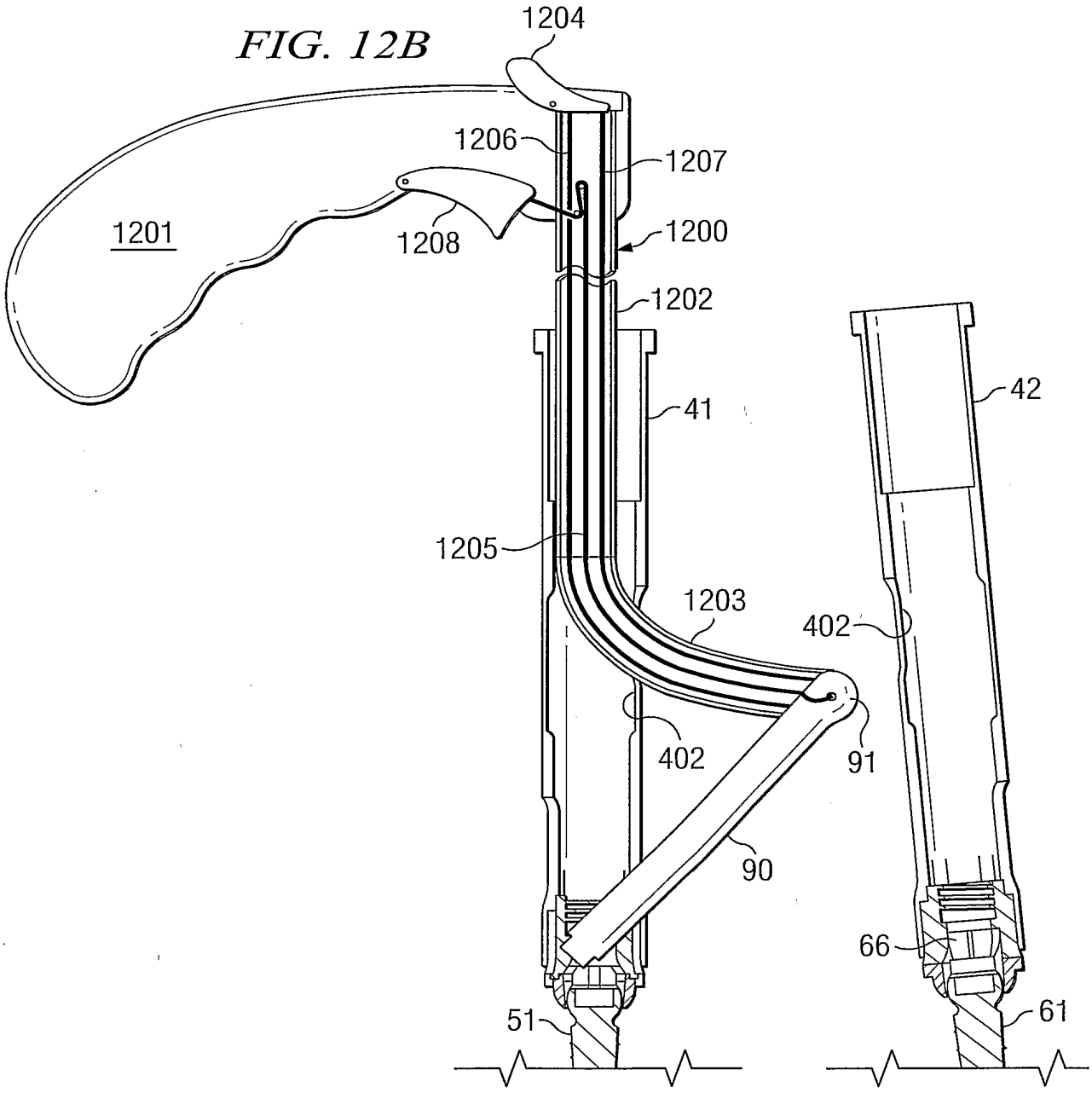
FIG. 12B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INTERNATIONAL SEARCH REPORT

Inter nal Application No
PCT/US2004/035000

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B17/88 A61B17/70

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
P,X	WO 2004/017847 A (BOEHM, FRANK, H., JR; MELNICK, BENEDETTA, D) 4 March 2004 (2004-03-04) abstract; figures 3,12	1,20,23, 25
P,X	WO 2004/041100 A (SPINAL CONCEPTS, INC) 21 May 2004 (2004-05-21) figures 79a-80c	1,11,20, 23,25
X	US 2002/138077 A1 (FERREE BRET A) 26 September 2002 (2002-09-26) abstract; figures 3a-3c	1,3,4,6, 10
A	US 6 530 929 B1 (JUSTIS JEFF R ET AL) 11 March 2003 (2003-03-11) cited in the application abstract; figure 1	1,11,20, 23,25

-/--

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

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"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
22 February 2005	02/03/2005

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Macaire, S

INTERNATIONAL SEARCH REPORT

Inter nal Application No
PCT/US2004/035000

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 2002/095153 A1 (JONES ROBERT J ET AL) 18 July 2002 (2002-07-18) abstract; figures 1-4	1,11,20, 23,25

INTERNATIONAL SEARCH REPORT

ational application No.
PCT/US2004/035000

Box II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 31-42
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

2. [ ] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

formation on patent family members

Inte pnal Application No
PCT/US2004/035000

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